

K070893

## 510(k) Safety Summary

---

March 2007

Submitted by:

CSA Medical, Inc.  
Emerging Technology Center  
1101 E. 33rd, Third Floor - #A305  
Baltimore, MD 21218  
O: 443.921.8053

MAY - 1 2007

Contact Person: Jennifer Cartledge, VP Development CSA Medical, Inc.  
(Direct Contact Number 864.506.0097)

### Name of Device

- Trade Name: CryoSpray Ablation System CU8407020500  
Directional Spray Catheter
- Common Name: Cryosurgical Unit, Cryogenic Surgical Device
- Classification: Cryosurgical unit with Liquid Nitrogen, Class II  
[21 CFR § 878.4350(a)].
- Establishment Registration Number: 9062377

### Predicate Devices

<u>Device</u>	<u>Premarket Notification</u>
SprayGenix™ Cryo Ablation System	K060555

### Company History:

CSA Medical, formerly CryMed Technologies received market clearance for the SprayGenix™ Cryo Ablation System (K060555). The name for the SprayGenix™ Cryo Ablation System was changed to the CryoSpray Ablation™ System as documented in the letter to file dated March 12, 2007.

### Device Description:

The CryoSpray Ablation™ System is used to destroy unwanted tissue by application of extreme cold to a selected site. Liquid Nitrogen is stored in a tank and then propelled through a cryo-catheter to perform the cryo-ablation procedure. The catheter, an accessory component of the CSA System, is placed in the appropriate position through the use of visual observation. The cryo-catheter applies the cryogen to a selected area and freezes the unwanted tissue. The catheter detailed in the K060555 submission is of a single lumen, straight tip design.

**Description of Modification:**

The only device modification presented in this Special 510k submission involves a tip configuration modification for the cryo-catheter. It was desirable to allow the end user's the ability to direct the cryogen radially. While the identical materials are used as compared to the catheter listed in submission K060555, the end of cryo-catheter is closed and a side hole is located in the distal side of the catheter, allowing a radial spray of the cryogen. All other dimensional specifications are identical to the catheter detailed in submission K060555. The surface area of the radial hole of the catheter is similar to the hole in the lumen opening of the straight spraying catheter. Refer to Attachments 5 and 6.

**Indications for Use:**

The CryoSpray Ablation™ System is intended to be used as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

The intended use of the modified catheter, as described in its labeling, has not changed as a result of the tip configuration modification. Refer to Attachment 3.

**Technical Characteristics:**

The modification to the catheter does not change the operating principals or mechanism of action for the CryoSpray Ablation System and it is substantially equivalent to the above listed predicate devices.

**Summary:**

Based on the principles of operation, design, materials and intended use, the modification to the Straight Catheter to produce a Directional Catheter results in a CryoSpray Ablation™ System that is substantially equivalent to devices currently marketed in the United States.

**Declaration of Conformity:**

Refer to Attachment 2.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

CSA Medical, Inc.  
% Ms. Jennifer Cartledge  
Vice President, Development  
1101 East 33<sup>rd</sup> Street, Third Floor - #A305  
Baltimore, Maryland 21218

MAY - 1 2007

Re: K070893

Trade/Device Name: CryoSpray Ablation™ System  
Regulation Number: 21 CFR 878.4350(a)  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: II  
Product Code: GEH  
Dated: March 26, 2007  
Received: April 3, 2007

Dear Ms. Cartledge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K070893

DEVICE NAME: CryoSpray Ablation<sup>TM</sup> System

CSA Medical, Inc.

**INDICATIONS FOR USE:**

The CryoSpray Ablation<sup>TM</sup> System is intended to be used as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X \_\_\_\_\_ or Over-The-Counter Use \_\_\_\_\_  
(per 21 CFR 801.109)

(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** 1090893